REMARKS

Applicants appreciate the opportunity afforded by the Examiner to make a further adjustment of the claims in response to the new grounds of rejection.

Section 102 Rejections

Two novelty rejections have been applied against different combinations of the claims. All of the claims stand rejected over one or the other of two references.

Claims 1-3, 5-7, 9-14, 16-21, and 23-25 stand rejected over US Patent 6,269,810 to Brooker et al.

Brooker et al. disclose a pulmonary dosing system and method that uses preparatory breaths (typically normal breathing breaths) for calculating the number of breaths required from an individual patient to inhale the necessary amount of a therapeutically active material. Pulsed amounts of the therapeutically active material are entrained in filtered atmospheric air. The entrained material is inhaled during subsequent breaths. The dosage is controlled by adjusting the pulse length and the number of patient exhales between pulses.

The present applicants have found that the inhalation maneuver distinguished by variables of flow and volume is important to the administration of the correct medicamentation dose to the lung in an optimal manner. In clear contrast to the disclosure of Brooker et al., according to the present invention, individual patient parameters and/or aerosol parameters are provided and used for the inhalation, and in particular, the respiratory flow and/or tidal volume are adjusted. The present specification acknowledges on page 2, lines 17-19, that every patient inhales at a different rate and with a different volume so that drug dosage within the lung varies widely. This problem is solved by the present invention so that the aerosol deposition in the lung can be predetermined and the desired dosage administered in a manner agreeable to patients, since the maneuver is adapted to the patients'

breathing capabilities (see for example page 3, lines 31-34, and item 1 of page 5 of the present specification).

Thus, in contrast to Brooker et al., the claimed invention adjusts the respiratory flow and/or tidal volume to the inhalation device. All three independent claims 1, 12, and 19 provide for the adjustment of individual aerosol doses by adjusting the respiratory flow and/or tidal volume to the inhalation device. This adaptation to patient capabilities provides for applying more optimal doses of medicaments to the lungs of different patients and can also accommodate changes in the pulmonary function of individual patients. New breathing maneuvers and changed respiratory flows can also be accommodated for the administration of different medicaments or for the application of medicaments to different sections of the patients' lungs.

Dependent claims 10, 18, and 25 further specify that the individual patient parameters and/or aerosol parameters for the inhalation are evaluated and, on the basis thereof, the respiratory flow and the tidal volume of the inhalation device are adjusted. Neither the adjustment of pulse length nor the adjustment of the number of patient exhales between pulses as proposed by Brooker et al. satisfies either part of the requirements for adjusting both the respiratory flow and the tidal volume of the claimed inhalation device. In addition, no appreciation of a need for making such adjustments is found in Brooker et al.

Claims 1-4, 6-22, 24, and 25 stand rejected over US Patent 5,560,353 to Willemot et al.

Willemot et al. disclose equipment and processes for supplying doses of at least one gas containing particles of an active product to the respiratory tracts of patients. Although coordinated with the breath phases of patients, the doses are controlled by regulating the number of discrete puffs of the gas through a nebulizer. Some patients receive more of the discrete puffs and others receive less. The number of doses, times, and dates of treatment are monitored.

Nothing suggested in Willemot et al. controls inhalation by adjusting the respiratory flow and/or the tidal volume of the inhalation device. Neither the inhalation flow nor inhalation volume is regulated by Willemot

et al.; both vary independently of the discrete puffs, which are superimposed upon the breathing maneuver.

Dependent claims 10, 18, and 25 further specify that the individual patient parameters and/or aerosol parameters for the inhalation are evaluated and, on the basis thereof, the respiratory flow and the tidal volume of the inhalation device are adjusted. No such suggestion, no appropriate means for carrying out such a suggestion, and no basis for even making such a suggestion are found in Willemot et al.

* * *

In view of the above amendments and arguments addressing the new grounds of rejection, applicants believe that the claims are now in condition for allowance. Accordingly, reconsideration and allowance of the claims 1-25 are respectfully requested.

For any question on these amendments, the Examiner is invited to call applicants' representative.

Respectfully submitted,
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TBR:cba
Enclosures
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